



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/584,183

01/03/2007

Eiji Sunahara

65792(46342)

1851

21874

7590

03/19/2009

EDWARDS ANGELL PALMER & DODGE LLP

P.O. BOX 55874

BOSTON, MA 02205

EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

03/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,183	Applicant(s) SUNAHARA ET AL.	
	Examiner ANNE L. HOLLERAN	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response to the restriction requirement mailed 11/07/2008 is acknowledged. Upon further consideration a new restriction requirement is set forth below.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, drawn to substances or agents that inhibit SEQ ID NO: 26, or agents that inhibit the binding of SEQ ID NO: 1, 4, 7 or 10 to SEQ ID NO: 26.

Group II, claim(s) 15 and 17, drawn to methods of screening for a substance that inhibits the activity of SEQ ID NO: 26, or substance that inhibits the binding of SEQ ID NO: 1, 4, 7, or 10 to SEQ ID NO: 26.

Group III, claim(s) 16 and 18, drawn to kits comprising SEQ ID NO: 26, or comprising SEQ ID NO: 26 in combination with SEQ ID NO: 1, 4, 7 or 10.

Group IV, claim(s) 19-23, drawn to methods of preventing or treating cancer by inhibition of the activity of SEQ ID NO: 26, or by inhibition of the binding of SEQ ID NO: 1, 4, 7 or 10 to SEQ ID NO: 26.

Group V, claim(s) 24, drawn to use a substance of claims 1 or 9 for making an agent for preventing or treating cancer.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the technical feature that appears to be common to groups I-V is not a special technical feature, where special technical feature is understood to mean a feature that makes a contribution over the prior art as a whole. The feature that appears to be common to groups I-V is that of the activity of SEQ ID NO: 26 as it relates to cancer. However, SEQ ID NO: 26 is the amino acid sequence of Plexin-B1, which is a receptor that is

Art Unit: 1643

known to play a role in the growth and survival of B-cell tumors (see Granziero, L. et al., Blood, 101: 1962-1969, 2003, March; cited previously), and to play a role in tumor growth by its binding to semaphorins (see Aurandt, J. et al. Proc. Natl. Acad. Sci., USA, 99(19): 12085-12090, 2002; cited in IDS). Therefore, inhibition of the activity of SEQ ID NO: 26 does not appear to be a feature that makes a contribution over the prior art as a whole.

The technical features of Group I is that of a substance that inhibits the activity of SEQ ID NO: 26, or the binding of SEQ ID NO: 26 to SEQ ID NO: 1, 4, 7, or 10.

The technical feature of Group II is that of method using SEQ ID NO: 26 to screen for substances that inhibit the binding of SEQ ID NO: 1, 4, 7 or 10 to SEQ ID NO: 26.

The technical feature of Group III is that of a protein that is SEQ ID NO: 26 or a combination of SEQ ID NO: 26 with SEQ ID NO: 1, 4, 7 or 10.

The technical feature of Group IV is that of a method using a substance that inhibits the activity of SEQ ID NO: 26 or the binding of SEQ ID NO: 26 to SEQ ID NO: 1, 4, 7 or 10.

The technical feature of Group V is that of use of a substance that inhibits the activity of SEQ ID NO: 26 or the binding of SEQ ID NO: 26 to SEQ ID NO: 1, 4, 7 or 10 to make a pharmaceutical composition.

Election of Species:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- a) antibody that bind to SEQ ID NO: 1, SEQ ID NO:4, SEQ IDNO: 7 or SEQ ID NO: 10
- b) antibody that bind to SEQ ID NO: 26 and inhibits the activity of SEQ ID NO: 26, or inhibits phosphorylation of SEQ IDNO: 26
- c) antisense nucleic acid that inhibits the activity of SEQ ID NO: 26 (see page 40 and page 55 of specification).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 2, 3, 4 and 11 read on species "a"
Claims 9, 10 and 11 read on species "b"

The following claim(s) are generic: claims 1, 5-8 and 12-14

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the antibodies of species "a" bind to proteins of the semaphoring 4B category, which is a separate and distinct class of protein from the proteins of SEQ ID NO: 26, to which the antibodies of species "b" bind, because SEQ ID NO: 26 is plexin-B1. Additionally, the antibodies of species "a" or "b" are separate and distinct compounds from the antisense of species "c", which is encompassed by "a substance that inhibits the activity" of SEQ ID NO: 26. Semaphorins and plexin-B1 are known in the art as evidenced by Granziero, L. et al., Blood, 101: 1962-1969, 2003, March), and Aurandt, J. et al. Proc. Natl. Acad. Sci., USA, 99(19): 12085-12090, 2002; cited in IDS). Therefore, antibodies that bind to plexin-B1 or semaphorins do not make a contribution over the prior art as a whole.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In re Ochiai:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

Art Unit: 1643

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
Monday, March 16, 2009

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643